



MAR 05 2010

The Honorable Mary Landrieu  
United States Senate  
Washington, D.C. 20510-1804

Dear Senator Landrieu:

Thank you for your letter dated January 14, 2010, in which you express concern about regulation by the Food and Drug Administration (FDA or the Agency) of imported shrimp products suspected to be contaminated with unapproved chemicals or antibiotics, such as chloramphenicol. You also encourage FDA to increase inspections of imported seafood, particularly shrimp.

We would like to assure you that seafood safety issues such as this are among the Agency's major concerns and are a top priority. Seafood products, and shrimp products in particular, are among the most internationally traded food commodities. Shrimp imports represent 94 percent of the total shrimp consumed in the United States. The vast majority of shrimp comes from aquaculture operations in Asian countries. Shrimp has been the most consumed seafood in the United States since 2001. For some time now, a key part of the FDA regulatory effort has been directed toward assuring that imported farm-raised shrimp products are safe for American consumers.

All imported products destined for the U.S. market must comply with applicable U.S. regulations and meet the same standards as domestic goods. Imported foods must be pure, wholesome, safe to eat, and produced under sanitary conditions. The FDA strategy for the safety of imported foods includes several components. All processors of fish and fishery products are subject to FDA's Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, commonly known as the Seafood HACCP (Hazard Analysis Critical Control Point) Regulation, 21 CFR Part 123.

This regulation requires both domestic and foreign processors of fish and fishery products to understand the food safety hazards associated with their process and product and, through a system of preventive controls, to keep those hazards from occurring. Under the seafood HACCP regulation, processors of farm-raised shrimp are expected to understand the hazard of unapproved chemicals and antibiotics and put in place preventive controls to ensure that their usage is legal and appropriate. The importer and the foreign processor share the responsibility for preventative controls of food safety hazards. Foreign processors that ship fishery products to the United States must operate in conformance with FDA's seafood HACCP regulation. In addition, importers are required to verify that the products they offer for entry were obtained from foreign processors that are in compliance with the requirements of the regulation.



The HACCP inspection approach is used by FDA during domestic and foreign inspections of seafood processors to focus attention on the parts of the process that are most likely to affect the safety of the product. Annually, FDA develops a “work plan” that outlines the Agency’s field staff’s domestic and foreign inspection responsibilities. Foreign inspectional coverage is based on product priorities as well as other country-specific factors, including the volume of seafood exported to the United States, the history of violations associated with the products originating from the country, the outcome of previous inspections of the seafood processors, the outcome of importer inspections, credible information raising safety concerns about a foreign establishment or country’s exports, and a processor’s use of a new technology or process that might raise food safety concerns.

Countries or individual firms that process and export aquacultured seafood are routinely targeted for inspection. In 2008, 87 inspections of seafood processors, including shrimp processors, were conducted in 16 countries. FDA also regulates imported seafood products by conducting inspections of importers, and by collecting surveillance samples of imported goods at the time of entry. FDA’s surveillance system for imports consists of reviews of prior notice data, reviews of shipment entry information for fish and fishery products being offered for entry into the United States, physical or sensory analysis (field examinations), sample collections for laboratory analysis of products awaiting entry, and detention of products with a history of problems. FDA routinely examines or analyzes fish and fishery product entries for microbiological contamination, decomposition, parasites, chemical contaminants (e.g., pesticides, dioxin, methyl mercury, and heavy metals), food and color additives, filth, mold, foreign objects, unapproved new animal (aquaculture) drugs, packaging, and labeling.

To prevent adulterated fishery products from entering domestic commerce, regulatory enforcement actions are taken against entries when violative samples are found. It is Agency policy to place violators on Import Alert (IA), and as a result, all subsequent shipments of product from firms on IA are subject to detention without physical examination (DWPE) at the time they are offered for import into U.S. commerce.

Shipments may be released by FDA if evidence (such as independent laboratory tests) can be provided by the importer demonstrating that the appearance of the violation (e.g., unapproved new animal drug residues) has been overcome and the product complies with applicable FDA regulations. In cases where FDA determines that a particular problem is widespread in a country or a region, the Agency may place all of a particular type of product from that country or region on DWPE. FDA also works closely with Customs and Border Protection to ensure that an IA is not circumvented through transshipment. Currently, there are nine active IAs that list processors or shippers of violative shrimp products due to the presence of residues from unapproved new animal drugs, contamination with *Salmonella*, decomposition, filth, and undeclared sulfites. This includes a countrywide Import Alert covering virtually all shrimp producers in China.

Furthermore, FDA has a continuous monitoring program. Under the program, samples of selected imported and domestic aquacultured seafood products are collected and tested



for the presence of unapproved chemical compounds, such as antibiotics and antifungal agents. The program's plan is prepared annually, with a collection schedule that is issued at the beginning of each fiscal year. A risk-based approach is used to identify particular products, countries of interest for each species, and drug residues to be tested. Sampling priorities are given to products and sources that have previously been found violative due to contamination with unapproved animal drug residues. Approximately 800-900 samples are analyzed each year, and shrimp account for 35 to 40 percent of the total number of samples. Results of testing allow the Agency to focus its attention on particular products or countries and to direct resources in a meaningful way.

In addition to the regulatory enforcement activities described above, FDA carries out assessment missions with exclusive focus on farm-raised seafood. The objective of these assessments is to evaluate the countries' animal drug residue control system for farmed fish in order to ascertain whether problems exist with implementation of their control measures, to determine what additional regulatory steps are needed, and to provide any necessary assistance. Since 2005, we accomplished five trips to countries that are the major producers and exporters of aquacultured products, including shrimp, to the United States. Some processors from these countries were listed as frequent violators. FDA is working closely with the authorities of these countries to help them take the necessary actions to strengthen their control over chemicals and antibiotics used in their aquaculture production and to ensure that seafood products are produced and processed in compliance with the U.S. food hygiene and safety criteria.

On December 11, 2007, the U.S. Department of Health and Human Services (HHS) and the State Food and Drug Administration (SFDA) of the People's Republic of China signed a Memorandum of Agreement to improve the safety of food, feed, drugs, and medical devices. One of the documents applies a strategy for establishing better controls over aquaculture products to ensure that these products meet U.S. standards for safety and quality. FDA is also engaged in negotiating a bilateral agreement with National Agro-Forestry and Fisheries Quality Assurance Directorate (NAFIQAD), the competent authority for fishery inspection in Vietnam regarding inspection of aquacultured fish and fishery products. FDA also provides technical assistance with the application of good aquaculture practices as a tool to control animal drug and chemical use, as well as information on U.S. laws and regulations regarding aquaculture products.

FDA, in cooperation with the Joint Institute of Food Safety and Applied Nutrition (JIFSAN), developed a train-the-trainer course, which is specifically designed for the aquaculture farming industry. The course, called Good Aquaculture Practices (GAQPs), is designed to assist aquaculture farmers and primary processors with guidance and recommendations on good management practices that are most appropriate for reducing hazards of pathogens (e.g., *Salmonella*), chemical contamination, and use of unapproved (or misuse of approved) chemotherapeutic drugs on the farm. The training was presented in three shrimp-producing countries: Vietnam, Indonesia, and Bangladesh. FDA intends to continue providing assistance with the application of good aquaculture practices for producers of domestic and foreign shrimp and other farmed-raised fish.

In recent years, a number of domestic and foreign food suppliers (such as producers, comanufacturers, or repackers) are increasingly looking to third-party certification programs to assist them in meeting U.S. requirements for safety and quality of foods. Some of them are required to become certified by third-party organizations in order to sell products on the U.S. market.

Recently, FDA conducted a pilot program to assess the third-party certification programs implemented by government agencies outside FDA and by private organizations. The pilot targeted certified aquaculture shrimp processors and associated certified farms and laboratories. The goal of the pilot was to explore the existing third-party certification programs currently available to aquacultured seafood (specifically shrimp) and gather technical and operational information that will assist FDA in determining their ability to meet FDA's requirements, and the extent to which certification programs provide adequate assurances of the safety of aquacultured shrimp from certified establishments. The shrimp pilot was recently completed and the acquired data are currently being compiled and analyzed.

FDA intends to continue the sampling and testing of shrimp and other seafood products with priority given to products and countries most frequently found to be in noncompliance and enforce its regulations to curtail entries of adulterated shrimp products from entering into interstate commerce. The Agency will continue to work closely with the foreign government authorities to provide any assistance that would support implementation of adequate controls over farmed seafood to better protect the American consumers and enhance the safety of the increasing volume of imports entering the United States.

We are hopeful that legislation already passed by the House will be considered soon by the Senate to update and strengthen FDA's food safety authority. New authorities, such as improved access to safety records, enhanced inspection, recall authority and others, as well as the additional resources that would be provided by registration fees, will modernize our food safety system and help meet the core principles identified by the President's Food Safety Working Group.

Thank you again for contacting us concerning this matter. If you have further questions or concerns, please let us know.

Sincerely,



Jeanne Ireland  
Assistant Commissioner  
for Legislation